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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/588,395	06/29/2007	Robert Gilmour JR.	19603/4612	8378

26774 7590 06/09/2009

NIXON PEABODY LLP - PATENT GROUP
1100 CLINTON SQUARE
ROCHESTER, NY 14604

EXAMINER	
PORTER, JR, GARY A	

ART UNIT	PAPER NUMBER
3766	

MAIL DATE	DELIVERY MODE
06/09/2009	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/588,395	GILMOUR ET AL.	
	Examiner	Art Unit	
	GARY A. PORTER, JR	3766	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *27 May 2009*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-38* is/are pending in the application.

4a) Of the above claim(s) *1-31,33,34,36 and 37* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *32,35 and 38* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *03 August 2006* is/are: a)☐ accepted or b)☒ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *1/16/2008*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Election/Restrictions

1. Applicant's election without traverse of Group V, Species 2, Sub-species C, i.e. Claims 32, 35 and 38 in the reply filed on 5/27/2009 is acknowledged.

2. Claims 1-31. 33, 34, 36 and 37 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to nonelected inventions and corresponding species, there being no allowable generic or linking claim. Election was made **without** traverse in the reply filed on 5/27/2009.

Specification

3. 35 U.S.C. 112, first paragraph, requires the specification to be written in "full, clear, concise, and exact terms." The specification is replete with terms which are not clear, concise and exact. The specification should be revised carefully in order to comply with 35 U.S.C. 112, first paragraph. Examples of some unclear, inexact or verbose terms used in the specification are as follows:

4. Paragraph [0061] states the following:

> "Figure 7 shows a histogram of type II conduction block at various S2 and S3 intervals generated from the wild type model. Note the presence of a large peak centered at an S2 very close to the minimum value for conduction and at an S3 approximately 50 ms longer than the minimum value for conduction. Surrounding the peak is a flat plateau region of five to ten blocks per bin that extends throughout the entire (S2, S3) region that was explored numerically. An overwhelming majority of these instances of block occurred after the S5 stimulus. However, six examples of 'early block' were found after an S4 stimulus, and one was found after an S3 stimulus. The latter explain the presence of the plateau in the histogram; the plateau is

made up of 'degenerate' counts in which long S2 or S3 intervals that maintained the initial S1 homogeneity were followed by early block intervals leading to block at S5."

5. It is unclear as to how the conclusions regarding S4 and S5 are obtained from Figure 7 since Figure 7 only discloses a histogram regarding S2 and S3. The Examiner can only find Applicants' statement that "the height at each point (S2,S3) space corresponds to the number of blocks found at beat S3, S4 or S5 for a given (S2,S3) pair (paragraph [0026]." Applicant has not defined a relationship between S2-S5 only that they are "a series of premature stimuli" (Paragraph [0023]). It is unclear as to how the timing of pulses S2 and S3 are connected or relate to S4 and S5, and thus it is unclear how the results of the histogram of Figure 7 are obtained.

6. Furthermore, in paragraph [0026], Applicant states "S2 min and S3 min are the minimum time intervals at points S2 and S3, respectively, that allow conduction down the fiber." The Examiner could not find in the specification the exact values Applicant associates with S2 min or S3 min. The terms are broad and inexact thus requiring further, specific definition.

7. In Paragraph [0066], regarding Fig. 10, Applicant states "shifting the curve from Figure 10D by subtracting 70 ms from f (M n+ 1, In) produced roughly the same number of blocks (94151) as in Figure 10D." It appears there is a typo but the Examiner is unable to Figure out what the first figure referenced is supposed to be. Applicant is required to clarify what specific curve is used for the base of subtraction, which results are shown in Figure 10D.

8. Furthermore, regarding paragraph [0066] and Figure 10, it is unclear as to what significance adding or subtracting 70 ms to a curve in the figure has. This time has no inherent meaning in and of itself and Applicant has failed to attribute any significance to this time shift. Further clarification and description regarding Figure 10 is required.

Drawings

9. New corrected drawings in compliance with 37 CFR 1.121(d) are required in this application because the images of the planar waves, the spiral waves and the multiple wavelets are too dark to draw any meaningful conclusions from. Furthermore, Figures 3, 5, 7-10, 12 and 14 are too dark and the images are too blurred to draw any meaning from. Applicant is advised to employ the services of a competent patent draftsperson outside the Office, as the U.S. Patent and Trademark Office no longer prepares new drawings. The corrected drawings are required in reply to the Office action to avoid abandonment of the application. The requirement for corrected drawings will not be held in abeyance.

Claim Rejections - 35 USC § 101

10. 35 U.S.C. 101 reads as follows:

> Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

11. Claims 32, 35 and 28 are rejected under 35 U.S.C. 101 because the claimed invention is directed to non-statutory subject matter. Specifically, Applicants' claims are

directed to a judicial exception of 35 U.S.C. 101. The method claims of the present application relate to abstract ideas, rather than practical application of those ideas. Specifically, the claims do not require any physical transformation and the invention as claimed does not produce a useful, concrete and tangible result. See MPEP § 706.03 (a). To overcome this rejection, and in regards to Claim 32, the Examiner recommends adding a tangible, useful and concrete method step wherein the method "employs" the "determining if an initial 3 stimuli in groups of 4 stimuli in the heart correspond to rest interval values…" by "performing an action" or "completing a method step" using a device/system. In other words, the result of this determination step must be used for some purpose within the method in order to overcome the 35 U.S.C. 101 rejection.

Claim Rejections - 35 USC § 112

12. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

13. Claims 32, 35 and 38 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for monitoring artificial electrical stimuli, i.e. stimuli applied by a medical device, does not reasonably provide enablement for all types of electrical stimuli, such as the natural electrical stimuli applied by the brain to the heart tissue. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to use the invention commensurate in scope with these claims. Specifically, Applicant claims monitoring "the electrical

stimuli in the heart of the subject." Given the broadest reasonable interpretation of the claims, the electrical stimuli could be any type of stimuli, such as artificial and natural electrical current. However, Applicants' disclosure only mentions applying premature artificial pulses to the body and also only mentions monitoring these artificial pulses (Paragraphs [0023, 0026, 0048, 0053, 0061]).

14. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

15. Claims 32, 35 and 38 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The Examiner notes that "the definiteness of the language must be analyzed, not in a vacuum, but always in light of the teachings of the disclosure as it would be interpreted by one of ordinary skill in the art. MPEP §2106"

16. Claim 32 recites the limitation "the electrical stimuli" in line 5 of the claim. There is insufficient antecedent basis for this limitation in the claim.

17. Regarding Claim 32, Applicant claims "identifying treatment candidates which prevent occurrence of a fourth stimuli corresponding to a rest interval value predicted to lead to ventricular fibrillation consistent with the histogram of Figure 7." The Examiner contends that one of ordinary skill in the art would not be able to discern what rest interval values are consistent with the histogram of Figure 7. The Figure itself is ambiguous and difficult to interpret, as noted in the Specification section above. Additionally, the Examiner notes that, regarding Claims, "incorporation by reference to a

specific figure or table 'is permitted only in exceptional cases where there is no practical way to define the invention in words and where it is more concise to incorporate by reference than duplicating a drawing or table into the claim.' MPEP §2173.05(s)." Applicant, therefore, must provide an exact range of rest intervals consistent with Figure 7 since it would a) be more concise to do so and b) be more exact than an interpretation of the figure, which could be interpreted differently as to what is "consistent" with the Figure. Furthermore, one of ordinary skill in the art would not be able to, without undue experimentation, replicate the test, whose results are shown in Figure 7, without some range of values or more specifics on what criteria were used to create the "approximately 67,000 combinations" that "produced conduction block")Paragraph [0053]). The Examiner understands that listing every combination would be burdensome and unnecessary, some outline as to how these values were chosen would be beneficial to alleviating the ambiguity of the specification and claims.

18. In regards to Claims 32, 35 and 38, where applicant acts as his or her own lexicographer to specifically define a term of a claim contrary to its ordinary meaning, the written description must clearly redefine the claim term and set forth the uncommon definition so as to put one reasonably skilled in the art on notice that the applicant intended to so redefine that claim term. *Process Control Corp. v. HydReclaim Corp.*, 190 F.3d 1350, 1357, 52 USPQ2d 1029, 1033 (Fed. Cir. 1999). The term "treatment candidate" in claims 32, 35 and 38 is used by the claim to mean "therapy" or, more specifically "electrical impulses", while the accepted meaning is "a person suitable fro

treatment." The term is indefinite because the specification does not clearly redefine the term.

19. With regards to Claim 38, the Examiner notes that "incorporation by reference to a specific figure or table 'is permitted only in exceptional cases where there is no practical way to define the invention in words and where it is more concise to incorporate by reference than duplicating a drawing or table into the claim.' MPEP §2173.05(s)." Applicant, therefore, must provide an exact range of the cardiac memory values consistent with Figures 10B and 10C since it would a) be more concise to do so and b) be more exact than an interpretation of the figure, which could be interpreted differently as to what is "consistent" with the figure.

20. Lastly, the invention as a whole as claimed in Claims 32, 35 and 38 is confusing and indefinite. As noted above, Applicant's disclosure describes applying 5 premature stimuli (S1-S5) (paragraph [0023]) in order to identify strategies for treatment or prevention of ventricular fibrillation or ventricular tachycardia (Abstract). However, in Claim 32, Applicant claims "identifying treatment candidates which prevent occurrence of a fourth stimuli corresponding to a rest interval value…." It is unclear how an electrical impulse, as recited in Claim 35, will or can prevent the application of a fourth artificial stimulus, i.e. S4. Applicant has only described in the specification monitoring and applying artificial stimuli to the body. Applicant has failed to clearly describe and point out how the treatment candidates are identified and how one or more artificial electrical impulses have the ability to preclude or interrupt another artificial electrical pulse, such as S4.

Claim Rejections - 35 USC § 103

21. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

22. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

23. Claims 32 and 35 are rejected under 35 U.S.C. 103(a) as being unpatentable over Snell et al. (U.S. Pub. 2005/0059897).

24. The following rejection is made with the Examiner's best understanding of the claimed subject matter in light of the 35 U.S.C. 101 and 112 first and second paragraph rejections.

25. Snell discloses monitoring ventricular activity via ventricular sensing circuitry, classifying the arrhythmia by comparing the intervals to predefined rate zone limits, and

in the case where a tachyarrhythmia is present, applying pacing therapy, i.e. one or more electrical impulses, to keep the arrhythmia from degenerating to fibrillation and to correct the arrhythmia (Section [0048]). Snell further discloses that the therapy is determined based on a classification system that uses histograms to classify the arrhythmia (Section [0086]). Lastly, Snell discloses monitoring a set number "N" of heartbeats before deciding the therapy to apply (Section [0093]; Fig. 17) but does not disclose monitoring exactly three stimuli, i.e. PQRS complexes (*a result of a stimulus at the SA node*) before classifying the arrhythmia. However, at the time the invention was made, it would have been an obvious matter of design choice to a person of ordinary skill in the art to monitor exactly three heartbeats before classifying the arrhythmia because Applicant has not disclosed that monitoring three heartbeats provides an advantage, is used for a particular purpose, or solves a stated problem. One of ordinary skill in the art, furthermore, would have expected the monitoring of any set number of heartbeats, and applicant's invention, to perform equally well with either the monitoring taught by Snell or the claimed method of monitoring exactly three stimuli taught by Applicant because both methods would perform the same function of determining if an arrhythmia was on the verge of turning into ventricular fibrillation equally well since both determinations form a histogram in which a therapy is derived.

26. Therefore, it would have been prima facie obvious to modify the method of Snell to obtain the invention as specified in claim 35 because such a modification would have been considered a mere design consideration which fails to patentably distinguish over the prior art of Snell.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to GARY A. PORTER, JR whose telephone number is (571)270-5419. The examiner can normally be reached on Monday - Thursday, 8AM - 5PM EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Carl Layno can be reached on (571)272-4949. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/G. A. P./
Examiner, Art Unit 3766

/Carl H. Layno/
Supervisory Patent Examiner, Art Unit 3766